DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for HIV, Hepatitis, STD and TB Prevention
[proposed]
Division of Tuberculosis Elimination

Advisory Council for the Elimination of Tuberculosis
December 5-6, 2006
Atlanta, Georgia

Record of the Proceedings

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List of Participants

ACET Members
Dr. Michael Fleenor, Chair
Dr. Jennifer Flood
Mr. Shannon Jones III
Mr. Joseph Kinney
Dr. Ana Lopez-De Fede
Dr. Masahiro Narita
Dr. Barbara Seaworth
Ms. Sirlura Taylor

***Ex-Officio* and Liaison Members**
Dr. William Baine (AHRQ)
Dr. John Bernardo (NTCA)
Dr. Amy Bloom (USAID)
Dr. Richard Ehrenberg (NIOSH)
Dr. Fred Gordin (ATS)
Dr. Michael Leonard (IDSA)
Dr. Mamodikoe Makhene (NIH)
Dr. Connie Mennella (NCCHA)
Dr. Lee Reichman (ACCP)
Ms. Rochelle Rollins
(HHS/Office of Minority Health)
Dr. Gary Roselle (VA)
Dr. Diana Schneider (DIHS)
Ms. Rachel Stricof (APIC)
Dr. Litjen Tan (AMA)
Dr. Theresa Watkins-Bryant (HRSA)

Designated Federal Official
Dr. Kenneth Castro,
Acting Executive Secretary

CDC Representatives
Dr. Kevin Fenton, NCHSTP Director
Ms. Sandy Althomsons
Dr. Gregory Armstrong
Dr. Stephanie Bailey
Ms. Regina Bess
Mr. Kevin Cain
Dr. Hazel Dean
Mr. Scott Danos
Ms. Mollie Ergle (Contractor)
Ms. T'Ronda Flagg
Ms. Maria Fraire
Ms. Judy Gibson
Dr. John Jereb
Ms. Josephine Jones
Dr. Dolly Katz
Ms. Ann Lanner
Dr. Phillip LoBue
Dr. William Mac Kenzie
Ms. Suzanne Marks
Ms. Kimberly McCarthy
Mr. Michael Melneck
Dr. Thomas Navin
Dr. Drew Posey
Dr. Robert Pratt
Ms. Sandy Price (Contractor)
Ms. Cathy Ramadei
Ms. Renee Ross
Mr. Joe Scavotto
Ms. Margie Scott-Cseh
Mr. Phillip Talboy
Mr. Sean Toney
Dr. Andrew Vernon
Dr. Charles Wells
Dr. Cornelia White
Dr. Carla Winston

Guest Presenters and Members of the Public
Ms. Jane Carver (International Union Against TB and Lung Disease)
Mr. Jim Cobb (National Tuberculosis Controllers Association)
Ms. Asma Henry (Public)
Ms. Molly Lindner (U.S. Agency for International Development)
Mr. John Seggerson (National Coalition for the Elimination of Tuberculosis)

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CENTERS FOR DISEASE CONTROL AND PREVENTION

ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
December 5-6, 2006
Atlanta, Georgia

Draft Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on December 5-6, 2006 at CDC's Corporate Square Facility, Building 8, in Atlanta, Georgia.

Opening Session

Dr. Kenneth Castro, the Acting ACET Executive Secretary, called the meeting to order at 8:30 a.m. on December 5, 2006. He announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. Members should be mindful of potential conflicts of interest identified by the CDC Committee Management Office and recuse themselves from voting or participating in these discussions.

Dr. Michael Fleenor, the ACET Chair, welcomed the participants to the meeting and particularly recognized the new ACET members, liaisons and *ex-officio* representatives. He pointed out that several items were placed on the agenda to orient the new members to ACET. These presentations would include an overview of the Federal Advisory Committee Act (FACA) and a review of ACET's mission, previous activities, accomplishments and future direction.

Dr. Fleenor opened the floor for introductions. The list of participants is appended to the minutes as Attachment 1.

Overview of FACA

Ms. Josephine Jones and Ms. Renee Ross, of the CDC Committee Management Office, provided an overview of FACA. FACA provides the legal foundation for establishing and

managing federal advisory committees (FACs). FACA formalized a process for establishing, operating, overseeing and terminating FACs. FACA ensures that advice rendered to the Executive Branch is both objective and accessible to the public.

The Congressional intent of FACA is as follows. A new FAC would be established only when it was determined to be essential. The FAC would provide advice that is relevant, objective and open to the public. Standards and uniform procedures would be developed to govern the establishment, operation, administration and duration of the FAC. Congress and the public would have knowledge of the purpose, membership and cost of the FAC. The FAC would be terminated after fulfilling the purposes for which it was established.

The role of FACs is to provide federal officials and the nation with advice on a broad range of issues affecting federal policies and programs. Recommendations that are fully discussed and voted on by FACs can be circulated to the head of an agency, a department, the General Services Administration (GSA), the President of the United States and Congress.

FACs can be represented by three types of members. Special government employees (SGEs) are private citizens who are appointed based on their individual expertise. SGEs are subject to standards of ethical conduct for employees of the Executive Branch. *Ex-officio* members are federal officials with expertise in the subject matter. As government employees, *ex-officio* members must also comply with the standards and principles of conduct outlined in FACA. Liaison members represent special interest groups, organizations or affected populations and are not required to adhere to FACA regulations.

FACA outlines specific responsibilities for FACs. Most notably, Congress, the President of the United States, GSA, agency heads and committee management officers have authority to oversee, manage and determine the usefulness, activities, organizational structure and function of each FAC.

FACA defines two types of FACs that can be established. A “mandated” FAC is authorized by statute or the President through an Executive Order. A “discretionary” FAC is formed when the head of an agency determines the need for external advice and recommendations. ACET is a mandated FAC. To formally establish a FAC, the agency must notify the public, file a charter, designate a federal officer (DFO), and appoint a chair and members.

FACA describes specific requirements to convene FAC meetings, including public notice, the presence of a DFO, opportunities for public comments, detailed minutes that are available to the public, and maintenance of committee records. FACs can form two types of subgroups to perform special tasks. Subcommittees must be represented by at least one member of the parent FAC, report directly to the parent FAC, and comply with FACA rules in accordance with CDC policy. The subcommittee must also present its recommendations to the parent FAC for deliberation.

Workgroups must be represented by at least two members of the parent FAC or subcommittee and report directly to the parent FAC or subcommittee. Workgroups conduct research, collect information and analyze issues related to the subject matter, but have no authority to make formal recommendations. Workgroups are not required to comply with FACA rules.

FAC members must adhere to financial disclosure and conflict of interest (COI) regulations while serving as SGEs. The Ethics Reform Act of 1989 requires each SGE to file a financial disclosure form upon appointment and annually thereafter. SGEs are prohibited from participating in any matter that would specifically and directly affect their financial interests.

The financial disclosure requirement was established for several reasons. SGEs and the agency would be protected. The FAC's activities would be performed without COIs or the appearance of COIs. The agency would be able to determine appropriate actions to take in the event a COI arises.

The law describes two major options for SGEs to remedy COIs. SGEs could publicly disclose their COIs and recuse themselves from participating in matters that affect their interests. SGEs could sign the agency's COI waiver that specifies requirements for recusal or participation in conflicting matters.

SGEs must also comply with other regulations in addition to COI rules. The bribery statute prohibits SGEs from seeking or accepting any item of value in return for being influenced during official government service. The representation statute prohibits SGEs from receiving compensation for representing an individual or an entity to the agency on any matter in which the SGE acted in an official capacity.

The post-employment statute imposes a lifetime ban on former SGEs representing an individual or entity to the government on any matter in which the former SGE personally and substantially participated during official government service. The Emoluments Clause of the U.S. Constitution prohibits federal employees from having a relationship with a foreign government or acting as an agent or lobbyist on behalf of a foreign entity without the consent of Congress.

The "Ethical Choice" video was developed by the U.S. Office of Government Ethics and was presented to ACET as a resource for the members to identify potential COIs. However, Ms. Jones and Ms. Ross emphasized that the ACET DFO or CDC Committee Management Office would be available to provide ACET members with guidance and assistance on determining COIs and identifying the most appropriate action to take. ACET members with questions on potential COIs should contact the CDC Federal Advisory Committee Management Team at 404/498-0090.

Dr. Castro provided additional details about ACET's specific role and function under FACA. ACET's advice does not result in financial decisions made by the Division of Tuberculosis Elimination (DTBE). Moreover, ACET members who are state or local health department officials do not influence the amount of funds CDC allocates to specific TB control programs.

In response to Ms. Stricof's suggestion, Dr. Castro agreed that ACET should adopt the practice of allowing members to publicly disclose potential COIs during the opening session of each meeting. To further increase ACET's transparency, he was also in favor of posting meeting minutes on the DTBE web site.

Dr. Castro announced that the current ACET charter would terminate on March 15, 2007. Efforts are underway to renew the charter, but the following change would be made in the "Structure" section. Management and support services would no longer be provided by the National Center for HIV, STD and TB Prevention Office of the Director due to CDC's reorganization.

In terms of communications, Dr. Castro explained that Dr. Fleenor, as the ACET Chair, has authority to discuss ACET's activities with the media. However, individual ACET members who are contacted by the press about matters that have not been discussed in a public forum should refer these persons to Dr. Castro.

Dr. Kevin Fenton, Director of the National Center for HIV, Hepatitis, STD and TB Prevention (NCHHSTP) [proposed], provided an update on changes in the FAC structure. In response to a request by the Director of the Coordinating Center for Infectious Diseases (CCID), a new Board of Scientific Counselors (BSC) was established and would convene its first meeting in the first half of 2007. The new BSC would have scientific oversight of CCID and its four national centers, provide advice on the quality of science, and examine scientific priorities. The BSC would not be subject to the same FACA rules as FACs.

Dr. Fenton announced that some of CDC's discretionary FACs are expected to be disbanded in deference to new BSCs throughout the agency. However, ACET is a mandated FAC and would be retained.

History of ACET

Dr. Fleenor reported that ACET was established in 1989 with a primary focus on the domestic TB agenda. ACET has increased its emphasis on the international TB agenda since that time due to common issues between the two agendas, such as disparities in minority and immigrant populations, infrastructure development and research.

ACET is a component of a larger operating unit and fulfills three major public health functions as a part of this charge. For "assessment," ACET has convened consultations on TB epidemiological and cultural trends. For "health policy development," ACET has formed workgroups, participated in consultation conferences, and developed TB guidelines. For "assurance and advocacy," ACET has provided advice to the CDC Director and HHS Secretary and engaged government, private and non-profit organizations in TB control and elimination activities.

Dr. Fleenor highlighted ACET's major initiatives from 2003-2006. In May 2003, ACET held a "TB Disparities in the Southeast" consultation to achieve three major outcomes. Awareness would be raised of disparities in TB rates between U.S.-born African Americans (AAs) and other U.S.-born persons. Support would be solicited to eliminate TB in U.S.-born AAs. Recommendations would be developed to accelerate the decline in TB rates among U.S.-born AAs in seven Southeastern states. Participants of the consultation included academicians, healthcare providers, public health leaders, policy and decision-makers, and AA organizations and agencies that could impact TB control efforts in AA populations.

ACET established a Foreign-Born Workgroup (FBWG) to achieve three major outcomes from November 2003 to June 2004. The focus and purpose of CDC's 1998 foreign-born guidelines would be determined. Consensus would be reached on evidence-based guidance. The guidelines would be updated with practical and useful information. FBWG was represented by ACET, CDC and other federal agencies, state and local TB control agencies, clinicians, immigration officials, non-governmental organizations (NGOs), minority health organizations and patient advocacy groups.

FBWG determined that the 1998 guidelines were not adequate to address the increase of TB in foreign-born persons. FBWG advised CDC to update the guidelines to address emerging foreign-born issues. CDC took several actions in response to FBWG's recommendations. A determination was made on the focus and purpose of the revised guidelines in June 2004. Efforts are underway to reach consensus on evidence-based guidance. A "TB in the Foreign-Born" consultation was convened in November 2006. The revision of the guidelines is expected to be completed in December 2007.

ACET made several recommendations to the HHS Secretary on foreign-born issues. Limitations in 45 CFR 400.107 should be waived. Health screening services should be provided to relocated immigrants. Funding for other public health services should be provided on the same basis of eligibility as states allocate dollars for other residents. Federal refugee medical assistance should be extended for refugees with TB infection until TB is fully treated. Federal funding should be augmented to allow heavily impacted states to hire staff to undertake this effort.

The HHS Secretary responded to ACET's recommendations on foreign-born issues in 2005. HHS shared ACET's concerns and made a commitment to continue to collaborate with international, state and local governments, healthcare providers and advocates to address

these issues. ACET also made several recommendations to the HHS Secretary on TB research. Annual funding for TB clinical trials should be increased by at least $10-~$25 million for the next ten years. Various HHS agencies should fully cooperate in new TB drug development. Funding for TB trials should not directly compete with existing TB control activities.

The CDC Director recently responded to ACET's recommendations on two issues on behalf of the HHS Secretary. For minorities and immigrants, CDC applauded ACET's interest and agreed with the problems in AAs and immigrants. CDC informed ACET that an AA conference was held in May 2006 in follow-up to the May 2003 TB disparities consultation. CDC suggested that the ACET Chair meet with the HHS Deputy Assistant Secretary for Minority Affairs. For TB funding, CDC responded that an increase in TB funding would be difficult due to multiple competing priorities. However, CDC committed to considering this issue in the President's 2008 budget.

In addition to communications with the HHS Secretary, ACET also made a number of formal recommendations to CDC from 2005-2006. DTBE should optimize TB and national public health preparedness collaborative efforts. CDC should recommend a reclassification of multidrug-resistant TB (MDR-TB) from a category C to a category B bioterrorism agent. The current restriction on using refugee health funds to complete health screening within the first 90 days after arrival should be waived for Hmong refugees who have resettled in the United States. The eligibility period for federal refugee medical assistance should be extended until TB infection or disease is fully treated in resettled Hmong refugees. Federal funding should be increased for states that are heavily impacted by Hmong refugees to hire additional public health staff.

A DTBE evaluation report on ongoing case management activities for Hmong refugees in Thailand should be developed and distributed to ACET. Collaborative efforts should be undertaken with the U.S.-Mexico Border Health Commission (BHC) to analyze data on the burden of binational cases. The BHC should be informed that the U.S.-Mexico binational TB referral and case management project would be discontinued in the near future if additional resources are not forthcoming. TB should be included on the HHS list of health disparities.

Additional comments were made on ACET's accomplishments. Dr. Diana Schneider, the ACET *ex-officio* representative to the Division of Immigration Health Services (DIHS), reported that DIHS developed a program for detainees in the custody of the U.S. Immigration and Customs Enforcement to continue and complete TB therapy prior to deportation from the United States. DIHS created the program in direct response to ACET's recommendation. DIHS is currently implementing the program at the national level and evaluating completion outcomes.

Dr. Castro announced that ACET received a federal advisory committee award in formal recognition of its productivity over the past few years. Moreover, ACET has increased awareness of TB in the HHS Office of Minority Health.

ACET was pleased with its diligent efforts and outstanding accomplishments over the past few years. However, several members expressed frustration on the slow and incremental progress that has been made in CDC and HHS responding to ACET's formal recommendations. The members made a number of suggestions for ACET to achieve a greater impact in the future.

- ACET should implement more dramatic and innovative strategies. For example, ACET could make a formal recommendation to CDC to change the name of DTBE to the "Division of Tuberculosis Control." Efforts could be made to engage Oprah Winfrey as a spokesperson for TB. An episode of a popular television program could be devoted to TB.
- A new liaison member representing a community advocacy organization for TB should be invited to serve on ACET.
- ACET should revisit its previous recommendation to hold a face-to-face meeting with the HHS Secretary.
- ACET should have regular attendance at HHS health committee meetings. This forum could be used to discuss the possibility of including TB on the HHS health disparities web page or adding a hyperlink to TB.
- ACET should explore strategies to incorporate TB into other care settings and emphasize the critical need for care from an individual rather than a disease perspective. For example, ACET could make a recommendation for the CCID national centers to focus on a coordinated care approach.
- ACET should use CCID's new BSC as a platform to reinforce the need to integrate HIV, STD and TB activities.
- ACET should make a recommendation for Health Resources and Services Administration (HRSA) community health centers and rural health centers to strengthen collaborative efforts with health departments. This approach would promote synergy and reduce silos at the local level. For example, HRSA health centers could attend meetings and serve on active committees of health departments to facilitate this type of relationship.
- Strategies should be developed to successfully and effectively integrate TB into community clinics without losing current capacity to control TB. CDC should include this effort in its research agenda.

NCHHSTP Director's Report

Dr. Fenton covered the following areas in his report. The name of the national center was changed to NCHHSTP in 2006 due to the new addition of the Division of Viral Hepatitis.

However, “NCHHSTP” is still proposed at this time because Congressional ratification of the reorganization has not been completed. An update on the FY’07 budget would not be provided because NCHHSTP’s continuing resolution would be in effect through December 8, 2006.

Dr. Fenton described changes in NCHHSTP’s senior leadership. Staff were appointed to serve in acting positions for the NCHHSTP Deputy Director, Associate Director for Health Disparities, Associate Director for Science, and Associate Director for Laboratory Sciences. Dr. Fenton expects to make more progress in 2007 to fill the acting positions with permanent staff.

Dr. Fenton outlined NCHHSTP’s six strategic imperatives. To “maximize public health impact,” NCHHSTP will align staff, strategies, goals, investments and performance to maximize its impact on the health and safety of populations. NCHHSTP established three FY’07 priorities to support this strategic imperative. The elimination of TB, syphilis and perinatal HIV will be accelerated. The implementation of hepatitis B, human papillomavirus and other vaccine-preventable STDs will be enhanced. The incidence and consequences of HIV/AIDS, hepatitis C and STDs will be decreased, particularly in racial/ethnic minority groups and resource-constrained countries.

To “ensure accountability,” NCHHSTP will sustain public trust and confidence by making the most efficient and effective use of investments in NCHHSTP. NCHHSTP established two FY’07 priorities to support this strategic imperative. Information about HIV, viral hepatitis, STD and TB prevention investments will be more easily and readily available to the public. Funding investments for HIV/AIDS, viral hepatitis, STD and TB prevention will be published on the NCHHSTP web site.

To “strengthen public health science,” NCHHSTP will create and disseminate knowledge and innovations for persons to protect their health now and in the future. NCHHSTP established three FY’07 priorities to support this strategic imperative. Training will be provided to promote scientific excellence within NCHHSTP. The ethical framework for HIV, viral hepatitis, STD and TB research will be adapted and refined. Workforce development will be promoted through internal and external research funded by CDC and its partners.

To “provide leadership,” NCHHSTP will leverage its unique capabilities, partnerships and networks to improve the health system. NCHHSTP established three FY’07 priorities to support this strategic imperative. NCHHSTP’s governance relationships and strategic priorities will be clarified and implemented. Leadership will continue to be provided at both national and international levels to improve health outcomes related to HIV, viral hepatitis, STD and TB prevention. Meetings will be convened with federal partners to enhance collaboration.

To “promote customer centricity,” NCHHSTP will market tools that persons desire and need to choose health. NCHHSTP established three FY’07 priorities to support this strategic

imperative. Existing partnerships will be sustained and strengthened. New and non-traditional partnerships will be developed to enhance the prevention and control of HIV, viral hepatitis, STD and TB. A communications plan that delivers accessible and comprehensive health messages to partners and the public will be developed.

To "strengthen global health efforts," knowledge and tools developed by CDC and NCHHSTP will be extended to promote health protection around the world. NCHHSTP established two FY'07 priorities to support this strategic imperative. The successful implementation of the President's Emergency Plan for AIDS Relief (PEPFAR) will be facilitated and supported. Collaboration with global surveillance, research and program partners will be fostered for the prevention and control of HIV/AIDS, viral hepatitis, STD and TB globally.

Dr. Fenton announced that NCHHSTP established two new strategic imperatives for FY'07. For "workforce development," NCHHSTP will facilitate and support the CDC-wide diversity initiative, employee career development planning and cross-training to meet future human capital needs. NCHHSTP established three FY'07 priorities to support this strategic imperative. Collaborative efforts will be undertaken with the CDC Office of Diversity to disseminate information on diversity policies, actions and initiatives related to diversity issues and trends. NCHHSTP managers will be educated on available resources to assist in recruitment and retention of a diverse workforce. Existing NCHHSTP resources will continue to be used to support training and career development.

For "surveillance and strategic information," NCHHSTP will harmonize data collection, analysis and distribution. NCHHSTP established two FY'07 priorities to support this strategic imperative. A cross-divisional surveillance workgroup will be convened to identify opportunities to harmonize data collection. The feasibility of producing an integrated annual surveillance report on HIV/AIDS, viral hepatitis STD and TB in the United States will be explored.

In addition to the strategic imperatives, Dr. Fenton noted that NCHHSTP would also place strong emphasis on two other areas to make substantial gains over the next few years. For "program collaboration and service integration," integrated services might include HIV, STD and hepatitis B and C counseling and testing; partner services and referrals to additional prevention or care; and hepatitis A and B immunization. Integration will be focused at the field or client level where the interface between the system and the consumer occurs. For purposes of this strategic imperative, NCHHSTP will define "integration" as an opportunity that results in integrated services for clients regardless of the agency structure.

NCHHSTP conducted several activities in 2006 to support this strategic imperative. Internal workgroups were formed. The NCHHSTP Director made site visits to explore opportunities for program integration. A new initiative was developed to cross-train project officers and program consultants. New information technology tools were designed to facilitate cross-

collaborations within NCHHSTP. Recruitment efforts are underway to fill a new position for the NCHHSTP Program Integration Associate Director.

For "health disparities," NCHHSTP will attempt to improve the health of populations disproportionately affected by HIV, STDs, TB and other related diseases or conditions to advance toward eliminating health disparities. Target populations for this strategic imperative will include racial/ethnic minority groups, women, incarcerated persons, and other communities and persons disproportionately affected by infectious diseases.

Several NCHHSTP divisions conducted activities in 2006 to support this strategic imperative. DTBE convened a consultation in May 2006 and launched the "Stop TB in the African American Community" web site. The Division of STD Prevention revised and released the "National Plan to Eliminate Syphilis in the United States." The Division of HIV/AIDS Prevention (DHAP) held a series of consultations and is now developing comprehensive plans to enhance HIV prevention among AAs. The need to incorporate STD, TB and viral hepatitis prevention strategies for AAs was emphasized during the consultations. Dr. Fenton confirmed that activities NCHHSTP conducted in 2006 for the program collaboration/service integration and health disparities strategic imperatives would be enhanced in 2007.

Dr. Fenton highlighted key areas in CDC's revised HIV testing recommendations for healthcare settings that were released in September 2006. For adults and adolescents, routine and voluntary HIV screening should be provided to all persons 13-64 years of age in healthcare settings. The screening should not be based on risk. HIV screening of persons with known risk should be repeated at least annually. Opt-out HIV screening should be offered with an opportunity for persons to ask questions and decline testing. HIV consent should be included with general consent for care.

For pregnant women, universal opt-out HIV screening should include HIV in the prenatal screening test panel. Consent for prenatal care should include HIV testing. A second HIV test should be offered to pregnant women in the third trimester who are known to be at risk for HIV or those who are in key jurisdictions or high HIV prevalence healthcare facilities. Opt-out rapid HIV testing should be offered to women with an undocumented HIV status during labor and delivery. Antiretroviral prophylaxis should be initiated on the basis of a rapid HIV test result. Newborns should be tested if the mother's HIV status is unknown.

CDC's revised HIV testing recommendations contain a "sunset clause" in which a specific healthcare setting could elect to discontinue HIV testing if the prevalence is found to be <0.1%. Low-incidence areas could then revert back to a risk-based testing strategy, but the prevalence of <0.1% must be documented. CDC expects to publish updated guidelines for HIV testing in community settings in late 2007 or early 2008.

Several ACET members expressed concerns about some of NCHHSTP's strategic imperatives.

- NCHHSTP should take caution in implementing the program collaboration/ service integration strategic imperative. Although this effort is feasible and has been successful in some settings, service integration was a major failure in the state of Florida and other metropolitan areas. Most notably, "program" integration typically results in "funding" integration and causes even larger budget cuts in TB control programs.
- NCHHSTP should eliminate barriers to local programs taking advantage of opt-out recommendations for HIV testing. For example, funds are allocated to TB and STD programs to complete and submit paperwork to meet the HIV reporting requirement. TB and STD programs would not release these funds to HIV programs and would be unable to offer opt-out HIV testing to patients.
- NCHHSTP should eliminate traditional barriers to integrating services at the local level. For example, CDC's policy of prohibiting HIV programs from releasing data does not allow TB programs to collect information and increase knowledge of HIV/TB co-infection rates.

Dr. Fenton made several clarifying remarks in response to ACET's concerns. NCHHSTP's program collaboration/service integration strategic imperative is not intended to combine budgets of individual programs. Instead, this activity is designed to maximize opportunities to provide more holistic care to patients, increase access to services, and advance prevention of infectious diseases.

For example, the Cook County Jail developed a service integration model in which each new inmate is screened for TB and syphilis and offered HIV testing during the intake process. Dr. Fenton encouraged ACET to provide NCHHSTP with solid and successful strategies that could be implemented to effectively integrate infectious disease services.

Dr. Fenton conveyed that CDC is aware of the critical need to modernize requirements for the collection of HIV data. NCHHSTP is currently exploring the possibility of implementing a tiered strategy to eliminate barriers to reporting requirements for HIV testing. CDC expects to release updated recommendations on HIV data reporting requirements in 2007.

Dr. Castro pointed out that NCHHSTP could take immediate actions to address some of ACET's concerns. NCHHSTP could change "integration" in the strategic imperative to "coordination" to promote the retention of subject matter expertise in each individual program. NCHHSTP could strengthen collaborations with partners to facilitate the dissemination and promulgation of the revised diagnostic, counseling and testing recommendations for HIV in TB clinics. NCHHSTP could reinforce ACET's previous recommendation for routine HIV counseling and testing of all persons with TB. Surveillance data could be compiled and distributed to states to promote this effort.

DTBE Director's Report

Dr. Castro covered the following areas in his report. In 2005, 14,097 TB cases were reported. The TB case rate of 4.8/100,000 was the lowest based on surveillance reports dating back to 1953. Of the 2005 cases, 54% were foreign-born with Mexico accounting for the largest burden. Of all reported TB cases, 28% were AAs and 29% were Hispanic. Of all U.S.-born TB cases, 47% were AAs.

The number of *M. tuberculosis* (*M.tb*) isolates genotyped by year increased from 4,950 in 2004 to 7,653 on October 31, 2006 with a future projection of 9,170. These data showed that 43.7% of culture-positive TB cases had isolates genotyped in 2004 compared to 75.7% in 2005. DTBE received five Epi-AIDS requests in 2006 to respond to TB outbreaks in diverse populations and settings.

DTBE expects to complete its revision of the reported verified case of TB (RVCT) in 2009. Comments will be solicited from partners prior to initiating the Office of Management and Budget clearance process. DTBE undertook this effort due to the need to incorporate new findings on extensively drug-resistant TB (XDR-TB) and binational TB cases.

DTBE is continuing to provide funding and support to four Regional Training and Medical Consultation Centers (RTMCCs) in California, Florida, New Jersey and Texas. The role of the RTMCCs is to increase capacity in TB programs through training, education and technical assistance; develop TB educational products; and provide medical consultation. The RTMCCs have made several major accomplishments to date. A comprehensive regional needs assessment was performed. More than 200 hours of training were provided to >500 participants each year. New education and training products were developed and disseminated. Medical consultation services were established. Mini-fellowships were offered.

DTBE is evaluating the RTMCCs to assess education, training and medical consultation services provided to TB programs. Interviews will be held with 60 project areas to support the evaluation. The results will be used to provide guidance to the RTMCCs to enhance the delivery of services.

DTBE released a competitive program announcement in response to ACET's recommendation in 2002 to address high rates of TB in the Southeastern part of the United States. Grantees would be required to develop, implement and evaluate interventions to reduce TB rates in AA communities within individual health jurisdictions. Chicago, Georgia and South Carolina were awarded funds under this project from 2002-2005.

The three project areas developed a number of interventions. AA outreach staff, peer educators who were former TB patients, health educators and a social worker were recruited. A TB task force was established with representation from all sectors of the

community. Social marketing campaigns were launched on World TB Day with the media and local celebrities. TB education and training materials, a video, rap song, pamphlets, posters and brochures were developed in partnership with the community and distributed to stakeholders. A toll-free telephone number was established for the community to ask questions about TB.

The Georgia and South Carolina projects have ended, but supplemental dollars were awarded in 2005 at a reduced level to continue key project activities. The supplemental funding will end in December 2006. Both CDC and the project sites developed fact sheets, posters, videos, web sites and other educational materials that will continue to be available to address TB in the AA community. DTBE awarded a contract to an academic institution to evaluate the Georgia and South Carolina projects and analyze interventions developed by all three sites.

Other TB resources include the HHS/CDC quarterly newsletter on eliminating TB in the AA community and a summit on stopping TB in the AA community co-sponsored by CDC and Research Triangle Institute. The summit resulted in several follow-up activities. A listserv and web site on stopping TB in the AA community were launched in August and September 2006, respectively. Conference calls were convened with workgroups established during the summit. Although current TB data should provide a strong rationale to support these initiatives, DTBE has not received sufficient funding to advance these activities through demonstration projects.

The TB Education and Training Network Conference and the TB Program Manager's Course were held in August and October 2006, respectively, with 226 participants. A resource page for TB behavioral and social science (TBSS) resources was launched in October 2006. Key features of the resource page include links to TBSS resources; a database on TBSS literature; TBSS research tools, surveys and guides; and a link to the TBSS listserv.

The TB Epidemiologic Studies Consortium (TBESC) is continuing its evaluation of new interferon-γ release assays (IGRAs) among ~2,500 healthcare workers (HCWs) who are routinely tested for latent TB infection (LTBI). The objective of the longitudinal study is to assess the feasibility, test characteristics and cost-effectiveness of IGRAs, the QuantiFERON-TB Gold in-tube test, T-SPOT TB, and tuberculin skin test (TST). HCWs will be retested every six months after initial testing for at least three re-tests. Sub-studies will be conducted on the cost-effectiveness, acceptability and usability of IGRAs by providers and patients. The four sites participating in the study are located in Denver, New York City, Maryland and Texas.

DTBE's final FY'06 budget was $138.8 million. Deductions from the budget included ~$1.4 million for a 1% HHS rescission; $5.3 million for CDC-wide assessments; $94,401 for a 1% redirection based on a request by the HHS Secretary; and a repayment to DHAP of

$500,000. Additions to the budget included ~$1.2 million from a readjustment by the CDC Financial Management Office and $8.6 million from DHAP to conduct joint HIV/TB activities.

Based on the deductions and additions, the actual TB ceiling for FY'06 was ~$141.3 million. However, this amount was $5.8 million lower than DTBE's FY'05 projection of $146.9 million. DTBE allocated the FY'06 TB ceiling as follows: 70% to prevention and control, 15% to DTBE and field expenses, 12% to TB elimination research, 2% to research support, and 1% to partnerships and communications.

DTBE anticipates a reduction of 5% or $7 million in the FY'07 budget based on the President's budget request of $136.5 million, House language of $137.4 million, and Senate language of $135.7. DTBE is awaiting rescissions and other budget information, but has assumed that the FY'07 ceiling would be $137.7 million. DTBE's assumption is based on a 1% rescission, the same CDC assessments and redirection of funds by HHS, 2.2% salary increases, a 2.2% increase in the cost of doing business, an allocation by DHAP, and the difference between the FY'06 and FY'07 ceilings.

DTBE has taken several actions in anticipation of the FY'07 budget cut. All branches are identifying potential areas for savings, such as travel, printing, salaries, information technology infrastructure, cooperative agreements and research projects. Conference calls were held with partners. ACET and the National Tuberculosis Controllers Association (NTCA) will continue to be updated about the budget through e-mail messages, but more formal communications will be initiated in mid-January 2007.

DTBE is considering several options in a five-year planning process based on an assumption of an overall reduction of 25% or 5% per year. For example, ~25 centers of excellence could be established with regional responsibilities instead of than funding individual TB programs. Regionalization could be centralized rather than distributed. Efficiencies gained from this effort could be articulated.

States could be asked to determine core functions, such as directly observed therapy (DOT), contact investigations, laboratory diagnosis, evaluation and genotyping. Support could be reduced for "non-core" functions. Either TBESC or the TB Trials Consortium (TBTC) could be closed. Major activities could be selected for reduction. The drastic reductions could be accompanied by changing the name of "DTBE" to the "Division of Tuberculosis Control" to strongly emphasize to decision-makers that DTBE would not be adequately funded to achieve TB elimination.

Dr. Castro encouraged ACET to provide DTBE with additional strategies to call more attention to the drastic reductions in the TB budget. For example, ACET could recommend that CDC develop measurable goals for each of its disease elimination or eradication programs, such as TB, polio, measles and syphilis. This approach would allow CDC to formally track, monitor and evaluate progress toward elimination.

Several ACET members emphasized the need to communicate with decision-makers who consistently reduce the TB budget each year. A number of suggestions were made on strong and accurate messages that could be delivered to decision-makers.

- More federal dollars are allocated to diseases that cause significantly fewer deaths than TB, such as smallpox and anthrax. The "shame" of the federal government in not increasing the TB budget should be publicly voiced.
- TB rates are not declining in other parts of the world outside of the United States.
- CDC should be given adequate support to serve as an international leader for TB funding and research.
- TB elimination is not occurring in local communities in the United States based on case rates of >100/100,000.
- The current and inaccurate perception of "TB elimination" does not allow collaborations with communities to be enhanced. Stronger relationships are needed for local agencies to develop interventions and increase access to TB prevention and treatment programs.

Overview of XDR-TB

Dr. Charles Wells, of DTBE, described potential implications of the global emergence of XDR-TB for TB control in the United States. MDR-TB is TB with resistance to isoniazid and rifampin. MDR-TB is caused by poor TB programs with low completion rates, poor clinical practices, an erratic drug supply, and poor quality of drugs. MDR-TB results in longer treatment up to 24 months with toxic regimens and a 10- to 100-fold increase in the cost per case. MDR-TB leads to lower cure rates of <80% and higher death rates with HIV co-infection. Poor infection control, MDR-TB and HIV could potentially lead to disaster.

Nosocomial MDR-TB outbreaks in the United States showed that HIV infection was associated with high mortality rates. In seven hospitals, the median interval between presentation and time of death ranged from 4-16 weeks. The global burden of MDR-TB is estimated to be ~425,000 cases annually. The Western Pacific region has the highest MDR-TB burden, while China, India and Russia are the top three countries with the highest incidence of new MDR-TB cases.

DTBE published a report in the March 24, 2006 edition of the *Morbidity and Mortality Weekly Report* (*MMWR*) on the emergence of XDR-TB. XDR-TB was originally defined as MDR-TB plus resistance to at least three of six major classes of second-line drugs. At least four classes of second-line drugs would be needed to effectively treat MDR-TB. The revised definition for XDR-TB was MDR-TB plus resistance to any fluoroquinolone and any injectable second-line drugs, including amikacin, kanamycin and capreomycin. Fluoroquinolones and injectable second-line drugs would be needed for better outcomes.

Based on a review of ~1,000 cases in Latvia, treatment success was 58% with the original definition and 35% with the revised definition. The review provided the basis to use the revised definition of XDR-TB.

XDR-TB is caused by inadequate MDR-TB treatment and second-line drug resistance. MDR-TB with resistance to multiple second-line drugs may be virtually untreatable. Cohort studies showed that ≥4 classes of drugs would be needed for MDR-TB treatment. CDC and the World Health Organization (WHO) administered a survey to 14 supranational TB reference laboratories from 2005-2006 to determine the extent of second-line drug resistance. Data were collected on >17,000 TB isolates tested by the laboratories from 2000-2004. Of all TB isolates included in the survey, 3,418 were MDR-TB, 10% were XDR-TB based on the original definition, and 7% were XDR-TB based on the revised definition.

An XDR-TB outbreak occurred in a rural province in South Africa. The death rate was 10% and all deaths were related to TB. Most of the patients had MDR-TB. A larger community investigation was launched to evaluate 1,500 patients presenting for hospital and clinic services. Of this cohort, 35% had culture-confirmed TB. Of the TB cases, 41% had MDR-TB. Of the MDR-TB cases, 10% had XDR-TB. All patients with HIV co-infection died with an interval of 16 days from presentation to time to death.

The impact of HIV on both MDR/XDR-TB is due to several factors. Public health systems are overwhelmed by the increasing burden of HIV-associated TB. Poor infection control and nosocomial transmission are common. Mal-absorption of anti-TB drugs occurs among patients with HIV/TB co-infection. Other reasons that HIV plays a role in MDR/XDR-TB include acquired rifamycin resistance, advanced immunosuppression, drug-to-drug interactions, use of isoniazid preventive therapy, and use of second-line drugs for concomitant illness. Botswana has observed an increase in anti-TB drug resistance as its case burden has increased.

A global task force was recently established with representation by CDC, WHO and Stop TB partners to develop a response plan to XDR-TB. In the short time, national TB programs would be improved. National level emergency plans would be developed. Rapid surveys of MDR/ XDR-TB would be administered within three to six months. Access to rapid rifampin drug susceptibility testing (DST) would be needed to facilitate this effort. The extent of the spread of MDR/XDR-TB would be determined. Current national TB laboratory capacity would be strengthened and expanded. Broad infection control measures would be urgently implemented with particular emphasis on persons living with HIV/AIDS.

In the long term, capacity to manage and treat MDR/XDR-TB patients would be established. Cases and contacts would be investigated and fast tracked for persons with HIV and those at high risk for MDR/XDR-TB. Referral centers would be established for MDR-TB treatment. Universal access to antiretroviral drugs would be promoted for all TB patients with HIV co-infection. Research for new drugs and diagnostics would be increased and supported. Research would be conducted on the management of case contacts.

Several activities are underway to address the global task force response plan. A coordinated global response to XDR-TB is being developed. Resources are being mobilized to raise a sufficient amount of funds to prevent delays in the response. Monitoring, evaluation and surveillance capacity is being expanded. A communications plan is being designed to promote a proactive flow of information to all stakeholders. Suspect XDR-TB cases are being rapidly identified for treatment. Appropriate infection control measures are being determined. Country support is being organized to respond to requests for assistance from resource-limited settings.

DTBE recently performed an analysis to identify countries that would be most likely to have a problem with MDR/XDR-TB. The analysis showed an overlap between countries of origin for foreign-born cases and those with a high MDR-TB burden and risk for XDR-TB. Mexico had the highest burden of MDR-TB cases in the Pan American Health Organization region. The Philippines had a high MDR-TB burden and Vietnam had a high XDR-TB burden.

XDR-TB has several implications for TB control in the United States. Laboratory and treatment capacity would be an important factor in addressing MDR/XDR-TB among immigrants and refugees. Capacity to capture drug surveillance data would need to be strengthened in the United States. Genotyping capacity would need to be maintained and expanded. Second-line DST would need to be standardized. The demand for U.S. laboratories to support reference laboratory functions would increase.

A negative impact on U.S. government initiatives to scale-up HIV treatment and care might occur. Increasing demands for outbreak response domestically and internationally would place more burden on staffing and resources at the state level. No precedent has been established for treatment of XDR-TB in the United States. Limited data have been collected on the efficacy of third-line drugs. Compassionate use drugs are under development. Safety monitoring programs would need to be established for these drugs.

The global approach would need to be closely monitored to increase knowledge in the United States of managing XDR-TB patients. No data have been gathered on managing case contacts or treating latent MDR/ XDR-TB infection. Policies and guidelines would need to be reviewed and updated based on the current emergence of XDR-TB. A coordinated response would be needed and resources would need to be leveraged across agencies. Interagency efforts could perhaps be facilitated by the existing Federal TB Task Force or a new comprehensive U.S. government response plan that includes a targeted research component.

A surge in resources would be needed both domestically and internationally. Most notably, U.S. resources have decreased and the global TB control investment has received flat funding over the past four to five years. The Global Fund for AIDS, TB and Malaria provides a minimal amount of resources for external technical assistance. Increased support by PEPFAR has been modest to date.

Ms. Suzanne Marks, of DTBE, announced that DTBE is performing analyses to determine the cost of treating XDR-TB cases in the United States. Preliminary findings showed that the cost of treating an XDR-TB patient would be over twice the cost of treating an MDR-TB patient based on the length of treatment. Total costs would be much greater if costs associated with long-term sequelae and deaths due to XDR-TB were included in the analyses.

Several ACET members made suggestions for CDC to consider in its ongoing efforts with partners to develop guidance for XDR-TB.

- Capacity should be developed to correctly use new drugs.
- A literature review of DOT should be performed. For example, published studies over the past five years concluded that DOT was ineffective, unnecessary and unfavorable.
- The implications of XDR-TB for TB control in the United States should be compiled and communicated as a strong advocacy tool to increase the TB investment.
- Surveillance data on MDR-TB in the United States should be improved. For example, existing surveillance data on initial or follow-up DST are not sufficient to determine whether the estimates of XDR-TB cases are accurate or complete. Existing surveillance data cannot be used to determine the burden of acquired drug resistance caused by TB programs in the United States. Existing surveillance data do not show the impact of TB budget cuts on preventing additional MDR-TB cases in the United States.
- States should be provided with data on the top countries of origin that are expected to account for the largest burden of XDR-TB cases. This information would alert states to potential fiscal implications in the future and would also assist programs in long-term planning.
- Stronger efforts should be made to gather better data from countries that do not have laboratory or surveillance capacity.
- An initiative should be launched to engage HIV programs in MDR/XDR-TB activities in terms of funding, coordination and advocacy. HIV programs should be informed that MDR/XDR-TB significantly affect the treatment and care of HIV patients.

Update on the Hmong and Burmese Resettlements

Dr. Thomas Navin, of DTBE, described TB screening that was performed for U.S.-bound refugees from Thailand. In January 2005, reports of MDR-TB in Hmong refugees who had resettled in the United States led to a review of the existing screening algorithm. In

February 2005, the screening algorithm was enhanced and specimen collection was improved. In October 2006, laboratory and program reviews were conducted.

The previous screening algorithm that was used prior to February 2005 is as follows. Persons ≥15 years of age were screened by chest x-ray. TST was not routine. Three smears were obtained for any individual with a positive chest x-ray. The enhanced screening algorithm that has been used since February 2005 is as follows. Persons ≥6 months of age are screened by chest x-ray. TST is applied to all persons <10 years of age. Three smears and three cultures are obtained.

The Hmong and Burmese resettlements involved three time periods, two algorithms, two populations and three laboratories. Before 2005, standard technical instructions were used to guide the screening of Hmong refugees in Thailand. The Thai National Laboratory performed DST. From 2005-2006, the enhanced screening algorithm was used to guide the screening of Hmong refugees in Thailand. The Thai National Laboratory and the International Organization for Migration (IOM) performed DST in Wat Tham Krabok.

The enhanced screening algorithm is now being used to guide the screening of Burmese refugees in Thailand. IOM will perform DST in Wat Tham Krabok and Mae Sot. IOM is using the MGIT machine that rapidly provides throughput and significantly enhances laboratory capacity.

Ms. Kimberly McCarthy, of DTBE, summarized results of her site visit in October 2006 to the Thailand laboratories. The site visit was made for several reasons. Current laboratory procedures for screening of U.S.-bound refugees in Thailand would be evaluated. Collaborative efforts would be undertaken with IOM staff on the development of laboratory performance indicators. Acceptable performance targets of the indicators would be determined. A process would be established for DTBE, IOM and the CDC Division of Global Migration and Quarantine (DGMQ) to report progress on the indicators.

In July 2005 and August 2006, the Wat Tham Krabok Laboratory and the Mae Sot General Hospital Mycobacteriology Laboratory, respectively, were established to respond to the need for improved TB laboratory screening of U.S.-bound Burmese refugees. The evaluation showed the following results. Laboratory practices were consistent with U.S. standards based on the use of concentrated acid-fast bacillus (AFB) smears, fluorescence microscopy, 1% concentration for specimen processing, conventional and automated liquid culture, biochemical and Gen-Probe identification, and DST with the MGIT 960. The Wat Tham Krabok Laboratory had solid performance, strong technical proficiency and well-trained microbiologists.

The following laboratory performance indicators were developed based on the evaluation results:

- The percentage of cultures reported as *M.tb* complex per month.

- The percentage of cultures reported as contaminated per month.
- The percentage of cultures reported as non-tuberculosis mycobacterium per month.
- The percentage of AFB-positive smears reported per month.
- The correlation between positive smears and positive cultures per month.
- The percentage of negative smears resulting in positive cultures per month.
- The turnaround time for smear, culture and drug susceptibility results per month. IOM's baseline goals for this indicator will be a 24-hour turnaround time, 21-30 days for identification, and up to 42 days for DST results.
- The performance of each staff member on external quality assurance (EQA) for AFB microscopy, proficiency testing for culture, and staff competency assessment.

Specific targets were developed for two of the laboratory performance indicators: (1) a contamination rate of 3%-5% and (2) quality assurance and competency of 80%-100%. Performance targets will be established for the *M.tb* complex recovery rate and the smear positivity rate after data are collected on the sampled population.

An evaluation was performed to compare the current performance and the established targets at the Wat Tham Krabok Laboratory. The results showed that the laboratory met or exceeded the indicators for the *M.tb* complex recovery rate, contamination rate, smear positivity rate, and quality assurance and competency. The laboratory also recently enrolled in an EQA program for microscopy and received a score of 100% in the second round. IOM management and staff made a commitment to implement the indicators. IOM management will monitor the indicators monthly and report results on a monthly basis to DTBE and DGMQ.

Dr. Gregory Armstrong, of DGMQ, presented program indicators and performance data for the Hmong and Burmese resettlements. Hmong refugees from Wat Tham Krabok in Thailand were divided into two groups. Cohort 1 was screened with the original algorithm that was developed before February 2005. The original algorithm was similar to the 1991 technical instructions. Persons with suspected TB were screened with smears. Cultures were performed only on smear-positive results. Chest x-rays were routinely performed on persons $\geq$15 years of age.

Cohort 2 was screened with the enhanced algorithm that was developed after February 2005. The enhanced algorithm was equivalent to the proposed revised technical instructions. Cultures were performed on all persons with suspected TB. Chest x-rays were performed on all persons $\geq$6 months of age.

Of 9,482 persons screened in cohort 1, 571 had suspected TB, 285 were diagnosed with pulmonary TB, and 21 had MDR-TB. Of 5,848 persons screened in cohort 2, 785 had suspected TB, 85 were diagnosed with either pulmonary or extrapulmonary TB, and 12 had MDR-TB. Of 357 pulmonary TB cases in cohorts 1 and 2 combined, 26 were smear-

positive and 91 were culture positive. Of 90 culture-positive cases with DST results in cohorts 1 and 2 combined, 33 were MDR-TB. Of 370 TB cases in cohorts 1 and 2 combined, all received DOT, 16 defaulted, five died, and one left for the United States prior to completing treatment.

Of 6,748 Burmese refugees in Tham Hin Camp in Thailand who were screened, 1,428 had suspected TB, 260 had diagnosed TB and 1 had MDR-TB. Of 260 pulmonary TB cases, 17 were smear-positive and 31 were culture-positive. Of 19 culture-positive cases with DST results, one had MDR-TB. Of 260 TB cases, all received DOT, 13 defaulted and one died.

Results of CDC's analysis of TB and drug resistance rates in the Hmong and Burmese refugees are as follows. Rates per 100,000 among the screened Hmong cohort 2 were 1,210 with pulmonary TB, 500 with culture-positive pulmonary TB, and 210 with MDR-TB. Rates per 100,000 among the screened Burmese cohort were 3,850 with pulmonary TB, 460 with culture-positive pulmonary TB, and 24 with MDR-TB. The MDR-TB rate among culture-positive cases was 36.7% in the Hmong cohort 2 and 5.3% in the Burmese cohort.

Several actions were taken to address problems that have surfaced over the past six months. To minimize delays in obtaining DST results, national TB laboratories have made improvements. IOM initiated DST in August 2006 to develop its individual DST capacity. Initial validation with the Australia supranational laboratory has been excellent.

To eliminate over-diagnosis of TB among the Burmese cohort, two IOM physicians attended a training course in Denver to strengthen their TB skills and obtain more knowledge on U.S. standards of diagnosis and treatment. The policy on initiating treatment was revised. Treatment would be initiated for all smear-positive persons. Physicians would wait for cultures for smear-negative persons unless the probability of TB was high. Therapy would only be initiated in consultation with the IOM/Thailand medical director.

The Tham Hin Camp incorporated an adverse event monitoring protocol into its TB treatment program. Baseline liver function tests (LFTs) are performed on all persons undergoing therapy. Follow-up LFTs are performed as needed. At the onset of therapy, patients are educated about the need to report potentially important symptoms. A physician performs an evaluation of each patient every one to eight weeks. A DOT nurse asks patients about symptoms that could indicate toxicity each day. Of 28 adverse events the Tham Hin Camp has recorded to date, 16 were minor, eight were suspected drug-induced liver injury, three were hyperuricemia, and one was niacin deficiency.

Dr. Armstrong summarized key findings of CDC's evaluation of program indicators and performance data on the Hmong and Burmese resettlements. The prevalence of TB was similar between Hmong and Burmese refugees. The prevalence of MDR-TB was much lower in Burmese refugees. IOM established a state-of-the-art and well-functioning TB laboratory. IOM is implementing routine collection of laboratory, screening and treatment indicators. ACET, DTBE and DGMQ will be involved in an onsite review in January 2007.

Update on Technical Instructions (TIs)

Dr. Drew Posey, of DGMQ, provided an update on the new TIs for overseas screening and treatment of TB. The DGMQ Immigrant, Refugee and Migrant Health Branch detailed a medical officer to Thailand to conduct regional oversight activities. The IOM laboratory expert who established the Wat Tham Krabok and Mae Sot laboratories entered into a contract with CDC to implement the new TIs, evaluate laboratory facilities and strengthen laboratory infrastructure overseas. Efforts are underway to hire a new medical officer to conduct regional oversight activities in Kenya.

CDC plans to initially implement the new TIs in Mexico, the Philippines, Vietnam, and Thailand for Burmese refugees at Mae La. CDC's rationale for initially targeting these countries is based on FY'05 data that showed 22.5% of immigrants to the United States from Mexico, the Philippines and Vietnam represented 66% of TB notifications and 44% of foreign-born cases in the United States. CDC will take several actions in preparation of implementing the new TIs overseas.

The United States received 36,376 immigrants from Mexico in FY'05 who were medically screened overseas. These immigrants accounted for 68 TB notifications. 1,942 foreign-born TB cases in the United States were from Mexico. CDC's site visit to Mexico in December 2005 showed that two panel physician groups perform all examinations in Juarez. In preparation of implementing the new TIs in Mexico, CDC will strengthen laboratory infrastructure and resolve issues related to DOT. CDC will conduct a follow-up site visit on December 12, 2006 to meet with the U.S. consulate and panel physicians and develop a concrete plan for next steps.

The United States received 33,684 immigrants from the Philippines in FY'05 who were medically screened overseas. These immigrants accounted for 2,857 TB notifications. 829 foreign-born TB cases in the United States were from the Philippines. The lead panel physician in the Philippines visited CDC in September 2006. CDC's site visit to the Philippines in September 2006 showed that one facility performs all medical examinations. Cultures are performed on smear-positive applicants and all applicants from other countries. DST is performed onsite and a DOT program is maintained onsite. In preparation of implementing the new TIs in the Philippines, CDC will strengthen laboratory infrastructure and resolve issues related to DOT for applicants not in Manila. CDC will conduct a follow-up site visit in January 2007.

The United States received 16,169 immigrants from Vietnam in FY'05 who were medically screened overseas. These immigrants accounted for 1,197 TB notifications. 577 foreign-born TB cases in the United States were from Vietnam. CDC's site visit to Vietnam in June 2006 showed that two panel physician operations jointly use the same laboratory and

treatment facilities. Cultures are performed on most smear-positive applicants and all applicants from other countries. A DOT program is maintained onsite. In preparation of implementing the new TIs in Vietnam, CDC will increase laboratory infrastructure and conduct a follow-up site visit in January 2007.

Highlights of the TIs are as follows. Panel physicians would be required to perform cultures on both smear-negative and smear-positive applicants. Smear-negative and culture-negative applicants would be required to be treated in the United States rather than overseas unless the panel physician determines that a delay in the initiation of therapy would be harmful to the patient.

Dr. Posey announced that DGMQ drafted an implementation plan for the new TIs in the summer of 2006. Based on comments from DTBE, DGMQ will develop an implementation manual to provide panel physicians with information on specific aspects of the new TIs. The manual will describe requirements for TST, chest x-rays, sputum smears, cultures, DST, DOT and data reporting. DGMQ will develop the manual with expertise from DTBE and expects to have a draft by June 2007. The manual will be designed for use by DGMQ and panel physicians. The document will be distributed to ACET and NTCA for review and comment.

DGMQ held an ad hoc meeting on November 17, 2006 with representation by ACET and NTCA. The goal of the meeting was to provide information to the TB community about the implementation of the new TIs and discuss strategies to improve communication and collaboration. Several documents were distributed to the participants: (1) the current draft of the TIs; (2) legislative and regulatory text that governs overseas evaluations of immigrants and refugees; (3) the draft implementation plan for the new TIs; and (4) a draft strategy for DGMQ to communicate updates on the implementation of the new TIs.

Agreement was reached during the meeting to accomplish several action items. ACET and NTCA leaders would review materials, provide comments to the leadership of their respective organizations, and forward comments to Dr. Posey. Drs. Fleenor and John Bernardo would serve as the organizational leaders for ACET and NTCA, respectively. A conference call would be held with representation by DGMQ, DTBE, ACET and NTCA following the March 2007 ACET meeting. Dr. Posey conveyed that DTBE and the CDC Office of the Director have cleared the new TIs. As a result, DGMQ does not plan to solicit additional comments on the text of the new instructions.

ACET was pleased that the current draft of the TIs reflected its previous comments. However, several members were still concerned about pediatric issues and other language in the TIs. For example, six weeks could pass between the time a young child presented with an infiltrate and a negative gastric aspirate was obtained. This time period could result in TB meningitis or other drastic outcomes to the child. Moreover, completion of complex MDR-TB cases overseas might be inappropriate. Although ACET was aware of the need to

implement the new TIs as soon as possible, several members were in favor of DGMQ resolving these issues before finalizing, disseminating and implementing the new TIs.

Dr. Posey made a number of comments in response to ACET's concerns. Efforts will be made to ensure that radiologists have experience in reading pediatric films and children are not presumptively treated. Considerations for children and pediatric patients will be extensively covered in the TI implementation manual. Although 15 years have passed since the 1991 TIs, DGMQ plans to revise and refine the new TIs on an ongoing basis.

Dr. Fleenor encouraged members who still had concerns about the TIs to submit these comments to him in writing. He would then forward these issues to Dr. Posey for DGMQ to consider in its ongoing review and update of the TIs.

Update on TB Activities in Mexico

CDC. Dr. William Mac Kenzie, of NCHHSTP [proposed], reported that foreign-born persons accounted for 55% of TB cases in the United States in 2005. Mexico accounted for 25% of foreign-born TB patients in the United States and 14% of the total U.S. cases. In 2004, states reported 1,979 TB cases among persons born in Mexico. Data from the Mexico National TB Program (NTP) showed that reported case rates of pulmonary TB in Mexico increased in 1996-1998 due to DOTS expansion and enhanced detection of cases. The number of reported cases declined in 2000, but the rate has been flat since 2004.

From 1990-2005, Mexico had a 71% decline in the mortality rate for pulmonary TB. However, the rate of 1.9 deaths/100,000 is still ten times more than the rate in the United States. WHO estimated TB cases and rates in Mexico in 2004 based on a population of 105.7 million persons. The estimates showed 33,529 new TB cases, a TB incidence rate of 32/100,000, 7,357 TB cases with previous treatment, and a TB prevalence rate of 39/100,000.

TB diagnosis in Mexico is based on smear positivity. No routine cultures or drug sensitivities are performed on new cases. Smear-positive cases are under-reported. A recent survey by the Mexican government showed that 30% of smear-positive TB cases reported in the laboratory were not entered into the TB registry. Primary care providers rather than specialty clinics treat new TB cases. Data collected in 2004 from 300 priority municipalities in Mexico showed that the policy of universal DOTS resulted in a 92% coverage rate and an 83% cure rate of new TB cases. However, these results are skewed because the 300 priority municipalities only represent 70% of TB cases in Mexico.

Culture and first-line DST are recommended for treatment failure in Mexico. DST results are significantly delayed and cultures are inconsistently performed because one national reference laboratory performs all DST. Treatment failures are referred to a state MDR

committee for management. Second-line DST is not available in Mexico. No regulatory authority has been established to confine active TB cases.

Primary treatment for new cases is two months of induction and four months of maintenance. Failed or relapsed cases are retreated with five first-line drugs for a longer induction period and the addition of ethambutol for five months during maintenance. Cases that fail re-treatment are given a standard second-line regimen with four drugs. Cases that fail the standard second-line treatment are given a second-line individualized regimen.

A 1997 study on TB drug resistance with data from three states in Mexico showed that isoniazid resistance was 19.1%, rifampin resistance was 9.6%, ethambutol resistance was 6.3% and pyrazinamid resistance was 5.4%. The overall MDR-TB rate was 7%; new MDR-TB cases were 2.4%, and previously treated MDR-TB cases were 22.4%. Based on U.S. data, Mexico accounted for three of 13 MDR-TB cases reported in the United States from 2000-2004.

TB laboratory capacity in Mexico is limited. AFB smear testing is performed by 650 laboratories. AFB cultures are performed by 31 state laboratories. First-line DST will be performed by eight regional laboratories beginning in 2007. Second-line DST will be performed by one national reference laboratory beginning in 2008. Mexico had a low HIV prevalence rate of 0.3% in 2003. In 1999-2000, <3% of commercial sex workers and intravenous drug users had HIV. Data collected by the Mexico NTP in 2006 showed that 3% of TB patients were HIV-positive.

Dr. Mac Kenzie described several activities that CDC plans to conduct in Mexico in collaboration with a broad range of partners. A national survey on TB drug resistance will be administered to 18 states as a population proportional sample. Smear-positive samples will be cultured to perform first-line DST on ~7,000 isolates. CDC will test ~500 rifampin-resistant isolates with second-line DST. Findings from the national survey will be used to drive policy, enhance knowledge, and encourage more DST in Mexico to prevent additional MDR-TB cases in the future.

Efforts will be made to establish a center of excellence with the following functions. Recognition, treatment and prevention of MDR-TB in Mexico would be enhanced. Education, training, consultation and case management would be provided through courses, mini-residencies, weekly case conferences and a toll-free telephone number. Information technology would be improved. Epidemiologic and laboratory data would be integrated to capture cases. Standardized reports would be provided to states and jurisdictions. Technical assistance on operational research would be provided.

U.S. Agency for International Development (USAID). Ms. Molly Lindner, of USAID, reported that USAID significantly contributes to the global reduction of morbidity and mortality associated with TB. USAID's objective is to enhance country capacity to prevent and cure TB and achieve global targets of a 70% case detection rate and an 85% treatment success

rate. USAID is the largest bilateral donor for TB and invested $93.3 million in TB resources in FY'05. Mexico and Brazil receive the most foreign assistance for TB control, but support to Mexico is 15 times more than that of Brazil.

The U.S. and Mexican governments signed a memorandum of understanding in 1999 and a TB bilateral cooperative agreement in August 2000 to support sustainable and effective institutional capacity to prevent, diagnose and control TB in priority areas. The agreement outlines a broad range of partners to conduct activities and manage funds; identifies 13 priority states in Mexico where the concentration of TB cases and migration continue to be concerns; and specifies goals and objectives to achieve over the next few years.

The agreement focuses on activities that will be conducted in three broad areas: (1) expand and improve DOTS activities at national and state levels; (2) support research; and (3) strengthen advocacy, communication and social mobilization. Specific projects that will be implemented under these areas are outlined below:

- An MDR-TB referral system.
- Laboratory quality control.
- A national study on MDR-TB.
- Operations research.
- An incentive program for the Mexico NTP.
- DOTS expansion.
- Social mobilization.
- A public/private mix initiative with associations, hospitals and private physicians to better integrate the Mexico national health infrastructure.
- Adoption of international standards for TB care.
- Provision of TB and MDR-TB clinical training.
- Development of an operational manual for the Mexico NTP.
- Monitoring and evaluation of U.S. government support.
- An information, education and communication campaign to increase awareness of TB.
- Donations of equipment to strengthen and update the existing infrastructure.
- Development of an integrated information system.
- Training on writing articles for submission to scientific journals.
- Technical training and personal development.

In addition to the bilateral TB agreement, USAID has made an investment of ~$22 million to date for TB control in Mexico. Small grants were awarded to seven Mexican and U.S. NGOs and support was provided to a number of U.S./Mexico university partnerships. However, USAID has discontinued its small grants program to coordinate, monitor, evaluate and oversee successful implementation of activities that were developed with these funds. Moreover, USAID and CDC entered into an interagency agreement to pass funds between agencies and jointly conduct activities.

Ms. Lindner was pleased to announce that Mexico has achieved several successes despite its tremendous challenges. For example, a program was developed to replace handwritten laboratory records with electronic data. TB health fairs and other activities are routinely conducted in local communities. Collaborative efforts were undertaken with a pharmaceutical company to develop an "all-in-one" pill for the standard first-line TB regimen.

An evaluation was designed to rank all Division of Health Promotion and Prevention programs and ensure that each state meets specific indicators. The Mexico NTP established four mobile TB units for states to provide onsite testing and make referrals in remote communities. A national network of nurses was created to address TB and serve as TB leaders in each state. TB materials are disseminated in schools to raise awareness about TB among children.

A mobile DOT program was developed. An initiative was created with both pre- and post-tests to raise awareness about TB and other health issues in communities with <2,500 persons. Communities with successful post-test results are given a white flag as a symbol of a "healthy community." The Dominican Republic and Haiti recently expressed a strong interest in replicating Mexico's binational TB card program. Mexico was the first country in the region to establish a national Stop TB committee. Since that time, 20 states in Mexico have formed Stop TB committees at the state level.

Dr. Schneider informed ACET of three key recommendations that were made at a recent meeting during Border Health Week. First, feedback should be provided to the border states on the future of the binational TB card program. The Mexico NTP expanded the program nationally and intends to further broaden this initiative between Mexico and Guatemala. Evaluation results showed that the program was successful in terms of referring TB patients who move from the United States to Mexico.

Second, BHC should develop a clearinghouse of legal information as a resource for the public health community in both Mexico and the United States. Laws included in the legal clearinghouse should be translated in both English and Spanish. Third, BHC should convene a legal symposium with representation by legal and public health experts from both Mexico and the United States.

Federal TB Budget Reductions and Program Integration

Dr. John Bernardo, the ACET liaison to NTCA, and Mr. Jim Cobb, the NTCA President-elect, provided NTCA's perspective on the impact of TB budget cuts and program integration. TB has implications for three major areas. For "medical" implications, TB diagnosis is often elusive. TB treatment is complex and lengthy, includes potentially toxic medications and requires technical expertise. Physicians, nurses, outreach staff and

programs are all responsible for successful treatment of TB patients. Laboratory support for TB is critical and unique compared to other infectious diseases.

For "social" implications, TB disproportionately affects underserved persons and is associated with stigma, economic costs to the public health system and communities, and access to care issues. For "public health" implications, TB is an airborne infectious disease that is a threat to communities. Although TB is a preventable disease, patients bear human costs in terms of morbidity and mortality.

In the early 1990s, ACET published the "Strategic Plan for Elimination of Tuberculosis in the United States" in the *MMWR*. The TB strategic plan called for a reinvestment in the current TB infrastructure, partnerships, shared responsibility, and specialized expertise in TB to advance from control to elimination.

ACET developed the TB strategic plan with five major components: (1) maintain control of TB through diagnosis and management; (2) accelerate the decline of TB through targeted testing and prevention in high-risk populations; (3) develop new tools through high-quality research; (4) engage global efforts; and (5) mobilize support. The goals of the TB strategic plan were to reduce the incidence to <3.5/100,000 by 2000 and reduce the incidence to <1/1 million by 2010. Based on the 2006 TB case rate of 4.8/100,000, the 2000 goal was not met and the 2010 elimination goal will not be achieved.

In response to the TB strategic plan, CDC developed a formula to award cooperative agreements to states, large cities and territories. NTCA's analysis of base funding to seven selected states from 2005-2006 showed that three states had increases in TB case rates ranging from 2%-5%; three states had decreases in TB case rates ranging from 6%-7%; and one state had no change in the TB case rate. Overall, 20 states had increases in TB cases in 2005. Base funding to the seven selected states ranged from $361,470-~$5.7 million in 2005 compared to $344,831-$5.4 in 2006. Funding to TB programs of ~$145 million in 2005 was nearly the same as the 1994 level.

NTCA solicited input from states on the impact of TB budget cuts. Comments by the seven selected states are summarized as follows. Alabama's TB case rate increased by 2% from 2005-2006. The overall budget from cooperative agreements, prevention block grants and state funds was reduced by 25%. A decrease in field staff resulted in compromised contact investigations and a dramatic reduction in DOT to patients since 2001. Georgia's TB case rate decreased by 6% from 2005-2006. The loss of personnel over the past five years included a nurse, outreach educators and physician assistants. Restrictions were placed on travel and training.

Minnesota's TB case rate did not change from 2005-2006. Funds to local health departments were discontinued, staff were reduced, and state laboratory services were decreased. The budget cuts occurred despite the fact that >5,000 Hmong refugees resettled to Minnesota in 2004-2005. New Mexico's TB case rate decreased by 7% from

2005-2006. Staff and several administrative functions were reduced, including follow-up and monitoring of completion of therapy and contact investigations. Washington State's TB case rate increased by 5% from 2005-2006. The elimination of education and training grants minimized expertise in the community for TB diagnosis. Reductions were passed to local health departments and travel was decreased by 30%.

Massachusetts' overall TB case rate decreased by 7% from 2005-2006, but TB case rates increased in foreign-born persons, U.S.-born persons of color and children. The elimination of nine federally funded positions since 2002 compromised capacity for nurses to perform case management in the field. Outreach staff were reduced by 56% and four clinics that offered free TB diagnostic and treatment services were closed. The elimination of targeted testing programs funded by CDC and the state minimized collaborative efforts with communities to identify high-risk persons and prevent TB.

Other impacts of TB budget cuts in Massachusetts included restrictions on travel, elimination of free laboratory services, and decreased capacity to accommodate new laboratory technologies. Shipping costs for genotyped samples increased from $55-$250 per sample. Overall, TB budget cuts have resulted in Massachusetts being unable to follow-up on contact investigations and complete preventive therapy in these cases.

Florida's TB case rate increased by 2% from 2005-2006. The governor stated that the Florida Department of Health could request budget authorities, but could not ask for additional legislative appropriations for TB control and prevention. A contract with the Florida Department of Corrections for TB control and prevention was not renewed. The contract totaled $116,723 and funded three full-time positions.

A contract with the American Lung Association of Florida for targeted TB testing in the HIV community and DOT to HIV/TB co-infected patients was not renewed. The contract totaled $66,243 and the county health department is now conducting these activities. Florida's TB central headquarters reduced its operating costs by $88,130 by reducing travel, eliminating equipment purchases and not filling vacant positions. Overall, the budget cuts will force patients in the state of Florida to seek care at community facilities that do not have specialized expertise and the necessary infrastructure for TB case management and treatment to cure.

Based on input from the states, the budget cuts will severely compromise implementation of the core components of TB control in the United States, such as planning and policy development; identifying and managing persons with clinically active TB and LTBI; providing laboratory and diagnostic services; collecting and analyzing data; and providing training and education. Although suggestions were made earlier in the meeting to change the name of DTBE to the "Division of Tuberculosis Control," the drastic budget cuts might eliminate current capacity to control TB.

With respect to the integration of HIV, TB and other communicable disease programs, several issues should be considered in the decision-making process. Most jurisdictions have already integrated services, but this practice is more common in low-incidence regions. The advantages of program integration include sharing an infrastructure and building coalitions. The disadvantages of program integration include a failure to recognize the unique need of the entire spectrum of TB services required by public health and the dilution or elimination of specialized resources, particularly in areas of greatest need.

Lessons learned from previous models of program integration should also be considered during the decision-making process. For example, a large city with a TB case rate of 11/100,000 integrated services in 2003-2004 and experienced a number of adverse outcomes. Clinical and public health expertise was minimized. The availability of TB clinical services was reduced and TST was eliminated. Several TBESC and TBTC activities were discontinued, such as population access to clinical research and community-based prevention programs, education and training.

Dr. Stephanie Bailey is a former ACET member and the new Chief of Public Health Practice at CDC. She informed ACET that the CDC Public Health Practice Office has a strong focus on performance standards, public health law, public health systems research, workforce development, translation of science to practice, and CDC-wide synergies for public health practice. In her new position, she would be committed to ensuring that community concerns, issues and practices would be included in CDC's decision-making process of developing policies.

With respect to ACET, Dr. Bailey acknowledged that reductions in the federal TB budget are of significant concern. However, she asked ACET to consider several issues during its efforts to call more attention to this problem. The public health community has not been effective in delivering evidence-based messages and presenting a strong business case to stakeholders to clearly demonstrate the impact of TB and other diseases.

Innovative and non-traditional strategies must be developed because resources will continue to be inadequate for TB and other diseases in the future. Existing structures should be identified and used to influence communities to prioritize TB and other health issues. A long-term rather than a short-term process should be developed to educate legislators and policymakers.

ACET was extremely concerned about the significant impacts on TB programs throughout the country as a result of budget cuts, particularly decreases in staff, weaker laboratory capacity, reductions in education and training activities, and compromised contact investigations. ACET agreed with Dr. Bailey that the TB community must take a new approach to increase the federal TB budget.

Several members suggested actions ACET could take as a leader or participant to raise awareness about the drastic TB budget cuts and more effectively convey the implications of these reductions for TB control in the United States in the future.

- Solid evidence and cost data should be compiled and widely disseminated to policymakers to demonstrate adverse events that could occur without adequate funding to TB programs in the United States. For example, the loss of the Florida Department of Corrections contract for TB control and prevention might result in more TB cases in correctional settings in the state. TB programs throughout the country will not have capacity to compete with new technologies that are being applied in the private sector, such as tele-medicine and the replacement of films with disks.
- Accurate messages should be delivered about TB budget cuts. For example, adequate funding for TB is still available, but decisions were made to divert funds to pandemic influenza preparedness and other urgent threats. Policymakers should be informed that a significant amount of federal dollars is being allocated to avian influenza, but this disease has caused minimal mortality to humans compared to TB.
- Advocacy should be strengthened at this time while long-term efforts are being made to collect evidence to influence Congress. For example, the media and local legislators should be informed that a current TB outbreak should not have occurred because TB is 100% preventable and curable.
- ACET should be more vocal and visible in its role as the only group of TB experts that advises the federal government.
- New relationships should be formed and resources should be leveraged with strong partners that serve the same populations affected by TB, such as HIV, diabetes and cardiovascular disease organizations. For example, the Centers for Medicare and Medicaid Services (CMS) recently piloted demonstration projects with pay-for-performance indicators and Health Plan Employer Data and Information Set measures for hypertension and diabetes. Providers participating in the pilot projects will be required to demonstrate tangible improvements in health outcomes for these patients. A CMS representative should be invited to a future ACET meeting to describe actions that can be taken to develop and link standardized TB initiatives to CMS's chronic disease framework. ACET could also use this opportunity to inform CMS that hypertensive and diabetic patients are also at high risk for TB.
- A strong champion should be identified to replicate the effective HIV message of "this silence must end" for TB and deliver this message to the Administration.
- ACET should communicate more direct, aggressive and stronger messages to the HHS Secretary. For example, the domestic TB program can no longer perform with continuous budget cuts and will ultimately fail. TB control cannot be maintained and TB elimination cannot be achieved without sufficient funding.

Dr. Fleenor noted that several agenda items might require ACET to draft and submit formal motions, recommendations or resolutions to the CDC Director or HHS Secretary. He confirmed that he and Dr. Castro would compile and present the list to ACET on the following day.

With no further discussion or business brought before ACET, Dr. Fleenor recessed the meeting at 5:30 p.m. on December 5, 2006.

Update on the TB Funding Formula

Dr. Castro reconvened the meeting at 8:40 a.m. on December 6, 2006 and yielded the floor to the first presenter. Mr. Joe Scavotto, of DTBE, provided an update on activities conducted by the TB Cooperative Agreement Funding Redistribution Workgroup. DTBE established the workgroup to address several challenges. Funding to TB control programs has declined. Human resource capacity and TB expertise have been lost. Program effectiveness and accountability are needed. TB cases have declined, but the remaining cases are more complex and require more effort.

The workgroup proposed several strategies to respond to the challenges. Core TB activities would be identified for grantees, such as case management for persons with TB disease, contact investigations, surveillance, laboratory capacity, program evaluation, training and human resource development. Performance measures and accountability for cooperative agreement funds would be established. A formula would be developed to redistribute 20% of FY'05 prevention and care funds. Redistribution of laboratory funds would be based on workload. Redistribution of 35% of prevention and care funds would be considered in FY'08 with a parallel process for laboratory funds.

In FY'05, programs received 80% of core financial assistance that was allocated in FY'04. DTBE placed 20% of funds in a redistribution pool that would be allocated based on a five-year average of morbidity and other factors, such as 40% of the total number of reported cases; 15% of the number of foreign-born cases; 15% of the number of U.S.-born minority cases; 10% of the number of A, B1 and B2 notifications; and 5% of the number of homeless, HIV co-infected, substance abuse and MDR-TB cases.

The workgroup is currently discussing whether the original amount of 20% or a new amount of 35% should be placed in the redistribution pool in FY'08. The workgroup is also considering whether funds should be redistributed, the proportion of funds to redistribute, and changes or additional factors that should drive the redistribution. The workgroup agreed that funds should continue to be redistributed in FY'08 and thereafter because this approach equitably distributes dollars among programs. The workgroup will continue to discuss potential adjustments to the formula based on new data or additional factors

identified in the future, such as XDR-TB. However, the workgroup's decisions are subject to change based on upcoming strategic conversations with TB controllers on future funding policies.

To date, the workgroup has received comments supporting both sides of this dilemma. On the one hand, more of the shrinking funding pool would be retained if the redistributed funds were less than 35% in FY'08. On the other hand, more gains would be obtained from the shrinking funding pool if the redistributed funds were more than 35% in FY'08. The workgroup will also consider key issues in the redistribution of laboratory funds. For example, a determination should be made on proceeding with the redistribution in light of existing budget cuts. The appropriateness of the formula or the need for modifications should be determined.

Dr. Fenton informed ACET that NCHHSTP [proposed] is currently exploring the possibility of developing redistribution formulas for HIV, syphilis and viral hepatitis to maximize its public health impact. DTBE will share its lessons learned to assist the other divisions in this effort.

Several ACET members made suggestions for DTBE to consider in its ongoing efforts to refine the redistribution formula.

- DTBE should compile and provide ACET with an adjusted redistribution formula that reflects regional patterns.
- DTBE should revise the redistribution formula to capture outcomes and problems because TB requires a long-term commitment by patients.
- DTBE should explore the possibility of releasing population-based program announcements for foreign-born persons, AAs and other high-risk groups.
- DTBE should perform econometric modeling of all expenditures by sector, such as laboratory, patient management and individual program costs. This approach would allow DTBE to determine a correlation between actual expenditures and TB morbidity in each jurisdiction.
- DTBE should revise the redistribution formula to eliminate huge disparities between the amount of funds allocated to states per TB case.
- DTBE should revise the redistribution formula to allocate more funds to the treatment of MDR-TB cases versus non-MDR-TB cases. Full funding of the MDR-TB case load would improve the surveillance system.
- DTBE should reconsider its "hold harmless" approach for low-incidence jurisdictions. Programs that receive <$250,000 are excluded from further redistributions.

Update on the Foreign-Born Workgroup (FBWG)

Dr. Dolly Katz, of DTBE, described FBWG's recent activities. ACET previously noted that CDC's 1998 guidelines for the prevention and control of TB in foreign-born persons were outdated. The current epidemiology of TB in the United States and in foreign-born persons was not reflected and important new data were not captured. For example, TBESC is completing a study on enhanced surveillance to identify missed opportunities for the prevention of TB in foreign-born persons.

ACET established FBWG in 2003 with the following charge. The focus and purpose of the guidelines would be determined. Consensus would be built and evidence-based guidance would be offered. The guidelines would be updated with practical and useful information. To fulfill its charge, FBWG formed five subgroups and solicited participation from TB control agencies, clinicians, immigration officials, NGOs, minority health organizations and patient advocacy groups.

The revised guidelines are organized into three major sections: (1) an introduction, (2) current requirements for the evaluation of foreign-born persons, and (3) recommendations and guidelines. Key topics in the recommendations section include a new screening algorithm, critical program elements, special issues for health departments, laboratory issues, specific foreign-born populations, critical partners, education and training resources, policy recommendations, and future research needs. A detailed draft outline of the revised guidelines was distributed to ACET for review.

The revised guidelines will be targeted to a broad range of audiences, including private physicians and other providers, community clinics, managed care plans, corrections facilities, NGOs serving foreign-born populations, congregate facilities, educational institutions, federal agencies, and state and local health departments.

FBWG held a meeting on November 16-17, 2006 and hopes to convene a progress meeting during the NTCA conference in June 2007. A small writing group will be formed to finalize the revised guidelines as a joint ACET/CDC document. The final draft is expected to be submitted to the CDC clearance process in December 2007. Dr. Katz encouraged ACET to provide Dr. Fleenor with additional comments on the draft outline of the revised guidelines.

Several ACET members made suggestions for DTBE to consider in its ongoing efforts to develop the revised foreign-born guidelines.

- A strategy should be developed to assist organizations in implementing the revised guidelines.
- The revised guidelines should include specific recommendations for foreign-born providers due to differences in medical education and training received abroad versus the United States. For example, many providers who were

educated and trained outside of the United States do not use isoniazid to treat TB.

- Input on the revised guidelines should be solicited from physicians in other countries to determine TB testing and treatment practices outside of the United States.
- The revised guidelines should be coordinated and consistent with the new international standards for TB diagnosis, care and treatment that have been disseminated throughout the world.
- The revised guidelines should be further modified to address early case finding of foreign-born persons who are not screened overseas.
- Existing opportunities should be used as a forum to present and disseminate the revised guidelines. For example, the National Association of Community Health Centers, homeless programs sponsored by the Migrant Clinicians Network, and other HRSA grantees convene conferences with representation by providers. Dr. Theresa Watkins-Bryant, ACET's *ex-officio* representative to HRSA, will assist DTBE in accessing these events.
- Web-based continuing medical education credits should be offered as an incentive for providers to use the revised guidelines.
- The American Medical Association (AMA) should serve as a key target audience for the revised guidelines due to its huge membership of primary care physicians and its specialty society of international medical graduates. Dr. Litjen Tan, ACET's liaison representative to AMA, will assist DTBE in reaching this audience.

Drs. Katz and Castro agreed with ACET that an implementation plan should be developed for the revised guidelines. In addition to ACET's suggestions, they also noted that consultations, conferences or regional meetings could be held; web-based seminars could be offered; and guidance could be given to providers on specific stages to implement the guidelines. Moreover, a TBESC workgroup was formed to focus on translating research into practice and could perhaps assist DTBE in developing the implementation plan.

Update on the Federal TB Task Force (FTBTF)

Dr. Philip LoBue, of DTBE, described FTBTF's response to XDR-TB. FTBTF was established in 1991 in response to the resurgence of TB and is represented by federal agencies with an interest in TB. From 1992-2003, FTBTF developed the "National Action Plan to Combat MDR-TB" and held monthly or quarterly tele-conferences. After 2003, FTBTF focused on the Institute of Medicine Report, *Ending Neglect: The Elimination of Tuberculosis in the United States*. FTBTF formed three workgroups to specifically address four recommendations in the report: maintain control, accelerate the decline, develop new TB tools, and increase global involvement.

FTBTF recently recognized the need to shift its focus to XDR-TB after an article was published in the March 24, 2006 edition of the *MMWR* on the urgency of this issue. FTBTF acknowledged that the U.S. government could play a role in six key areas of a coordinated global response to XDR-TB. One, surveillance of drug-resistant *M.tb* isolates and HIV/TB co-infected patients would be supported. Two, epidemiologic investigations would be conducted to identify risk factors for and transmission dynamics of XDR-TB.

Three, mycobacterial laboratory capacity would be built and enhanced in concert with HIV laboratory capacity. Field evaluations of rapid testing algorithms would be performed, such as bundle enhanced AFB microscopy and EQA. Four, practical infection control precautions would be implemented with priority given to persons living with HIV/AIDS in congregate settings. Five, capacity would be built to promptly recognize and properly manage patients with highly resistant forms of TB, particularly in the context of HIV antiretroviral therapy and other preventive therapy. Six, research would be conducted to evaluate and develop new and accurate diagnostic and effective treatment regimens.

FTBTF took several actions in response to the potential role of the U.S. government in the coordinated global response to XDR-TB. During a conference call that was held in November 2006, FTBTF agreed to form workgroups to address the six key activities. The workgroups will focus on surveillance, epidemiology and outbreak investigations, laboratory capacity, infection control, clinical and programmatic issues, research and communication.

FTBTF will use the 1992 MDR-TB action plan as a model in developing a new U.S. government action plan for XDR-TB. FTBTF will hold additional conference calls with the next call scheduled on December 12, 2006. FTBTF will convene its annual face-to-face meeting earlier than September 2007 due to the urgency of XDR-TB.

Several ACET members made comments for FTBTF to consider in its ongoing discussions on XDR-TB.

- FTBTF should ensure that case management and the need for better surveillance of MDR/XDR-TB cases in the United States remain as prominent issues in discussions on the global response to XDR-TB. FTBTF should review data collected by RTMCCs to guide these discussions.
- FTBTF should increase its advocacy efforts because policymakers and other groups outside of the federal government have no knowledge of the urgency of XDR-TB.
- FTBTF should emphasize the critical need to increase capacity of both domestic and international TB programs in preventing MDR/XDR-TB. For example, MDR/ XDR-TB are manmade diseases that are only caused by the inability of programs to properly perform case management, administer DOT and deliver other TB services.
- FTBTF should ask the American Thoracic Society and the Infectious Diseases Society of America to revise the guidelines on the management of

community-acquired pneumonia. Isolated use of fluoroquinolones is recommended as a second-line alternative drug regimen, but the guidelines should be modified to include specific qualifications for TB.

Dr. Castro made several remarks in response to ACET's comments. DTBE agrees with ACET that the urgency of XDR-TB should be communicated outside of the federal government. DTBE briefed the CDC Director on this issue and hopes to provide the same information to the HHS Secretary. However, testimony on XDR-TB should be given to Congressional members and other elected representatives. DTBE will solicit assistance from ACET, the Stop TB Partnership, international organizations, TB experts and other partners in providing credible testimony on the urgency of XDR-TB.

With respect to ACET's concerns about the need for the U.S. government to continue to focus on the domestic TB agenda, Dr. Castro confirmed that DTBE would immediately respond and provide technical guidance to states with relatively large burdens of MDR-TB in need of epidemiologic assistance. During future discussions, he encouraged FTBTF to explore opportunities to perform rapid evaluations of new TB diagnostic tests in these settings. He pointed out that FTBTF should focus on the respective roles of CDC, the National Institutes of Health, and the Food and Drug Administration in these discussions.

Update on TB Informatics

Ms. Sandy Price, a CDC contractor, and Mr. Scott Danos, of the CDC National Center for Public Health Informatics, provided an update on TB informatics. All states and territories now report data from RVCT through the Tuberculosis Information Management System (TIMS). TIMS was developed in the mid-1990s as a client/server-based system. Multiple state databases and a CDC database in TIMS are synchronized. RVCT data are transferred by modem on a monthly basis.

CDC will replace TIMS with the National Electronic Disease Surveillance System (NEDSS) TB program area module (PAM) after 2008. The NEDSS TB PAM will be a web-based system that will not require a modem. Messaging of RVCT data will be instant. Only one state database and the CDC database will need to be synchronized.

The NEDSS initiative represents CDC's largest public health information technology surveillance project. NEDSS components include a national vision for integrated surveillance systems, standards for system design and electronic messaging between systems, NEDSS-related funding, a NEDSS base system (NBS), a NEDSS PAM platform (NPP), implementation guides, NEDSS message subscription services, and a NEDSS link.

NPP is a specific implementation of NEDSS standards and includes two major components: (1) a common services platform that crosses program areas and disease conditions and (2)

individual disease- and condition-specific PAMs. NPP has 5,700 functional capabilities and 1,200 business plans. The TB PAM includes RVCT, a transition approval process and data migration for TIMS. Future releases of the TB PAM could capture data on antibiotic microbial sensitivity and resistance. In addition to the TB surveillance PAM, NPP also contains PAMs for lead and varicella. A new STD PAM is expected to be completed in mid-2007 and will facilitate contract tracing and partner notification for varicella and TB.

As of November 13, 2006, 56 sites were developing NEDSS or deploying or producing NBS. Ohio was the first beta site for NPP and is finalizing its review of these results. The user acceptance test of NPP is expected to be completed on December 20, 2006. The first production of NPP will be released based on results of Ohio's review and comments. A demonstration web site is now being finalized and will be accessible to partners for review and comment.

CDC took several actions to ease the transition from TIMS to NEDSS. A technical document was developed with information on the costs of NPP for hardware, software, technical support and software maintenance for commercial tools. The annual cost for the commercial software applications that are bundled with the NPP are approximately $15,000. Depending on the size of the state (number of concurrent users and number records entered per year), the hardware and software costs associated with the implementation of the NPP may vary from approximately $100,000 to $150,000. Specialized technical support for this application are also required. The TB PAM was designed with similar features as TIMS to familiarize users with the new system. To date, 30 states have expressed an interest in using the TB PAM.

The CDC Public Health Information Network "Case Notification Implementation Guide for TB" is undergoing the final clearance process and is expected to be posted on the CDC web site over the next week. The technical document outlines the content and structure for TB case notifications to CDC and will serve as a model for all states to submit data to CDC.

ACET was pleased that NEDSS will drastically improve the capability of states and local jurisdictions to collect and submit data to CDC to better guide the direction of TB programs.

ACET Business

Dr. Fleenor entertained a motion to accept the previous meeting minutes. The motion was properly moved and seconded by Mr. Jones and Dr. Lopez-De Fede, respectively. The July 26-27, 2006 ACET Meeting Minutes were **unanimously approved** with no changes or further discussion.

Dr. Fleenor listed ten business items that might require ACET to draft and submit formal motions, resolutions or recommendations to the CDC Director or HHS Secretary.

1. XDR-TB.
2. Face-to-face meeting with the CDC Director or HHS Secretary to express two major concerns: (1) a change from TB elimination to control and (2) the response required to maintain the focus on TB elimination.
3. Request by the Migrant Clinicians Network for a formal ACET recommendation to assure continued funding of TBNet and binational projects.
4. Technical instructions.
5. A new ACET liaison member representing the Treatment Action Group (TAG) and TAG's presentation to ACET on the global state of TB research.
6. Development of CDC goals for its disease elimination and eradication programs, including TB.
7. Promulgation by DTBE of the latest HIV testing recommendations in healthcare settings for TB patients seen in TB clinics, including the development of a link to the DTBE web site.
8. Follow-up to the May 2006 disparities conference, including ACET's coordination with this group and other strategies to address disparities.
9. U.S.-Mexico activities and coordination with USAID.
10. Engagement of CMS to develop pay-for-performance indicators for TB services.

ACET took three actions to address business item 1. Dr. Bernardo read a resolution into the record that was drafted on the previous day.

> *Whereas*, recent increases in multidrug-resistant TB (MDR-TB) in the United States and the March 24, 2006 *Morbidity and Mortality Weekly Report* documented the emergence of extensively drug-resistant TB (XDR-TB) globally and in the United States, noting that patients in the United Sates with XDR-TB were 64% more likely to die during treatment than patients with MDR-TB;
>
> *Whereas*, the documented real threat of airborne spread of XDR-TB in the Untied States portends an epidemic of incurable TB that is far worse than most currently "high profile low threat" diseases;
>
> *Whereas*, the current FY'06 federal funding level for the Division of Tuberculosis Elimination (DTBE) of $137.4 million represents a substantial decrease over the past decade and dramatically compromises the necessary investment in human resources and capacity for simple TB control, much less elimination;

Whereas, DTBE has been advised of potential further budget reductions of 5% in anticipation of FY'07 appropriations eroding our front-line public health defenses;

Whereas, the costly resurgence of TB between 1985 and 1992 and confirmed reports that 20 states had case *increases* in 2005, indicating once again that the United States is neglecting its responsibility to the public for the prevention and control of TB;

Whereas, the 2.4% decline in cases in 2004 represents the smallest annual decrease in the number of new cases reported since the devastating upsurge in incidence since the early 1990s; and

Whereas, the United States has failed to provide adequate resources for applied research for the development of new tools for the improvement of diagnosis and treatment of TB.

Now, therefore, be it resolved that the Advisory Council for the Elimination of Tuberculosis unanimously recommends that the Director of the Centers for Disease Control and Prevention and the Secretary for Health and Human Services seek an urgent supplemental appropriation for Health to fully fund DTBE at $252.4 million, the level recommended by the National Coalition for Elimination of Tuberculosis and based on recommendations from the Institute of Medicine Report, *Ending Neglect: The Elimination of Tuberculosis in the United States*.

Several ACET members made comments on the draft resolution.

- ACET should solicit specific input on surveillance from DTBE in revising the first "whereas" paragraph.
- The language in the second "whereas" paragraph should be revised to "high profile urgent threat diseases."
- The language in the third "whereas" paragraph should be revised as follows. The FY'06 federal funding level to DTBE should be changed to $138.8 million to accurately reflect the Congressional appropriation. "Current" should be deleted because FY'06 has ended.
- Language should be added to the last paragraph of the draft resolution to clarify that the purpose of the request for full funding to DTBE is to increase the capacity of programs to identify cases, provide case management and assure completion of TB treatment. The new language should also note that the inability of programs to provide these services has resulted in XDR-TB.
- ACET should take a two-step approach on the draft resolution. The document should be revised, formally approved and submitted to the HHS Secretary at this time, but more drastic actions should be taken over the next

year. For example, ACET should compile data and develop a report or formal statement that emphasizes the failure to control TB at the state level and eliminate TB at the national level. Discussions on XDR-TB and insufficient TB funding in the report should serve as the basis to provide focused recommendations on the needs of TB programs. This approach would allow AMA and other partners to issue press releases or hold conferences to publicly support the ACET report or formal statement. An ACET report would also have a wider reach to Congressional decision-makers and the public.

Dr. Castro announced that DTBE was required to develop language to describe critical program needs. He pointed out that ACET was free to use all or part of the language in revising the draft resolution.

> XDR-TB is an emerging problem at a time when the U.S. budget for TB elimination dwindled. This erosion, foreseen in the Institute of Medicine's 2000 report entitled *Ending Neglect*, is causing degradation of state and local public health capacity at a time when a new and more resistant form of TB is spreading. Other signs, such as a slow rate of decline, sporadic outbreaks, racial disparities and TB in the foreign-born, point out that the United States is barely maintaining control, let alone reaching its goal for elimination.

A motion was properly placed on the floor and seconded by Drs. Fleenor and Flood, respectively, for ACET to adopt the draft resolution with the changes noted for the record. **The motion was unanimously approved.**

Dr. Fleenor read a draft cover letter to the HHS Secretary into the record that would accompany the resolution.

> The accompanying resolution reflects the unequivocal convictions of the Advisory Council for the Elimination of Tuberculosis (ACET) that our nation is facing a crisis of unprecedented proportion caused by untreatable and highly fatal strains of TB. Unless we take immediate measures, we anticipate an inability to protect the public from an imminent airborne biological threat posed by extensively drug-resistant TB (XDR-TB). The ultimate responsibility for assuring the safety of U.S. citizens rests with our nation's public health system that is led by the Department of Health and Human Services (HHS) and coordinated by the Centers for Disease Control and Prevention (CDC).
>
> We have watched the slow dismemberment of a program which over the last 15 years has driven incidence rates of TB to the lowest levels in the history of Public Health Service. Through progressive and regressive cuts in funding to the Division of Tuberculosis Elimination (DTBE), even the ability to control TB is in question, much less elimination of the disease. This goal was established by HHS in [date]. More and more, this has forced states and

local jurisdictions to absorb costs of control efforts that legitimately falls to the federal government to sustain.

ACET has reached the regrettable conclusion that it is no longer possible for CDC to fulfill its mandated task of TB elimination. Given this shrinking federal funding base, we should no longer delude ourselves or the nation that elimination is achievable. Consequently, ACET must recommend to you and the Director of CDC that without restoration of adequate federal funding, both DTBE and ACET be renamed to reflect the fiscal realities that impose a retreat from the achievable goal of elimination to control of TB in the United States.

This said, we cannot stand by without making a final appeal to you and the Director of CDC to avoid this outcome. We ask for a special urgent appropriation to restore funding to DTBE as a first step to the return to the noble and achievable goal of elimination of TB in the next decade in the United States.

Several ACET members made comments on the draft cover letter to the HHS Secretary.

- The letter should be revised to list partners that will receive copies of the letter.
- "Crisis of unprecedented proportion" should be deleted from the first paragraph.
- The second paragraph should be revised to clarify that TB rates declined, but will increase in the future due to funding cuts to DTBE.

ACET agreed to form a new "Funding Implications Workgroup." Dr. Fleenor described the preliminary charge of the new workgroup. First, a comprehensive, strategic and evidence-based review of the implications of funding cuts to DTBE would be conducted. Second, intermediate- and long-term recommendations would be formulated. This guidance would be designed to resolve the erosion of capacity in the United States to address the emerging TB problem and improve the ability of the country to eliminate TB.

Third, a strong advocacy component would be incorporated into the workgroup's activities to ensure the delivery of concordant messages among all partners. The workgroup would be given a timeline of six to eight weeks to fulfill its charge by the end of January or mid-February 2007. Dr. Flood volunteered to chair the workgroup; Drs. Fleenor and Reichman volunteered to serve as members.

Dr. Fleenor announced that time constraints would not permit ACET to discuss or take action on the remaining business items. As a result, he summarized next steps to address these issues.

- Dr. Fleenor would immediately revise the cover letter and draft resolution to the HHS Secretary. He would circulate the new drafts to ACET for a final review by December 8, 2006.
- Drs. Fleenor and Castro would coordinate the new "Funding Implications Workgroup." E-mail messages would be circulated to solicit additional volunteers from ACET and DTBE to serve as members. The first conference call would be scheduled for the workgroup to refine its charge.
- Dr. Fleenor would participate in a conference call with DTBE over the next two weeks to discuss the remaining business items and identify agenda items for the next meeting.

The action item and agenda items raised over the course of the meeting are outlined below.

Action Item

- The DFO will provide ACET with a summary of the December 2006 CDC/ HHS Health Disparities Research Agenda meeting.

Agenda Items

- Update on ACET's recommendation to reclassify MDR-TB as a category B bioterrorism agent.
- Presentation by Mr. Mark Harrington of TAG on worldwide funding of TB compared to other diseases.
- A series of presentations on TB disparities.
- Discussion on options to restructure ACET meetings: (1) a longer period of time on day 1; (2) an extension to two full days; (3) less presentations on day 2 and a longer period of time for ACET business; and (4) the willingness of voting members to remain for a longer period of time.

Closing Session

The next ACET meeting will be held on March 20-21, 2007. With no further discussion or business brought before ACET, Dr. Fleenor adjourned the meeting at 12:10 p.m. on December 6, 2006.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

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Date

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Michael E. Fleenor, M.D., M.P.H.

ACET Chair